UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,965	06/20/2006	Ezio Bombardelli	2503-1189	7314

466 7590 01/30/2009

YOUNG & THOMPSON
209 Madison Street
Suite 500
ALEXANDRIA, VA 22314

EXAMINER	
ML QIUWEN	
ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
01/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,965	BOMBARDELLI, EZIO	
	Examiner	Art Unit	
	QIUWEN MI	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-10 and 13* is/are pending in the application.

4a) Of the above claim(s) *3,6-8 and 10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,9 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

CONTINUED EXAMINATIONS

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/08 has been entered.

Applicant's amendment and Declaration in the reply filed on 9/15/08 is acknowledged, with the cancellation of Claims 5, and 11-12. Claims 1-4, 6-10, and 13 are pending. Claims 3, 6-8, and 10 are withdrawn as they are directed toward a non-elected invention groups or species. **Claims 1, 2, 4, 9, and 13 are examined on the merits.**

The election of species to the first vasoactive agent is hereby withdrawn.

Any rejection that is not reiterated is hereby withdrawn.

Specification/Abstract Objections

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, Applicant is required to delete "The invention relates to" on line 1 of the Abstract to be more clear and concise. The first letter of "combination" in line 1 should be capitalized after the deletion.

Claim Objections

Claims 1, 2, 4, 9, and 13 are objected to because of the following informalities: Claims 1 (line 10) and 13 (line 7) recite "*Gingko*", which is incorrect. The correct spelling should be "*Ginkgo*".

All other cited claims depend directly or indirectly from objected claims and are, therefore, also, objected for the reasons set forth above.

Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4, 9, and 13 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Di Pierro (WO 02/098436 A1), in view of Thiolon et al (An in vitro, ex vivo, and in vivo demonstration of the lipolytic effect of slimming liposomes: an unexpected alpha-2-adrenergic antagonism, J. Cosmet. Sci., 53: 209-218, 2002).

Di Pierro discloses a pharmaceutical and/or cosmetic composition for the treatment of cellulite comprising 0.1-2.5% complex of escin/beta-siterol with phospholipids (the third vasoactive agent), 0.1-2.5% complex of *Gingko biloba* dimeric flavonoids with phospholipids (the second vasoactive agent) etc (page 2, lines 20-28). Di Pierro also teaches that the complex of escin/beta-sitosterol with phospholipids has the same action as escin, but shows a more prolonged release of the active principles and improved bioavailability (page 3, lines 10-13); and the complex of *Gingko biloba* dimeric flavonoids with phospholipids, has the same activity as the dimeric *Gingko biloba* flavones in the free form, but shows a more prolonged release of the active principles and better bioavailability. *Gingko biloba* dimeric flavonoids are extremely potent vasoactive agents due to their inhibitory action on the release of histamine and of the enzyme cAMP phosphodiesterase from mast cells (page 3, liens 13-20). Di Pierro further teaches that the composition of the invention will be formulated in the form of cream, oil, gel, foam, emulsion, milk (page 4, lines 15-20).

Di Pierro does not teach the incorporation of the first vasoactive agent esculoside, or the claimed amount of esculoside into the composition.

Thiolon et al teach a SLC slimming liposomes containing two microcirculation activators, i.e., esculoside and Centella asiatica extracts, one phosphodiesterase inhibitor, i.e., caffeine and one fatty acid-beta oxidation activator, i.e. L-carnitine (page 209, synopsis, 1st paragraph). Thiolon et al teach the composition is able to reduce the thigh circumferences of human volunteers by more than 10 mm. More than 20% of the human volunteers participating in the test had their thigh circumferences reduced by more than 10 mm, whereas, in the same time, their other, non-treated, thigh did not show any circumference reduction. This last study shows the

potent slimming effect of SLC and furthermore emphasizes the relevance of our "slimming approach" (page 216, 2nd paragraph).

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that it is deemed that the prior art product must not be precluded for use as a vasoactive agent. It is deemed that the composition disclosed by Di Pierro and Thiolon et al. is not precluded for carrying out the intended function of the claims.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the esculoside from Thiolon et al to treat cellulite Since Thiolone et al teach the composition containing esculoside reduces the thigh circumferences. Since both of the compositions yielded beneficial results in "slimming" effect, one of ordinary skill in the art would have been motivated to make the modifications to combine them together.

It has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. The differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference

process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). see MPEP § 2144.05 part II A. Although the prior art did not specifically disclose the amounts of esculoside, it would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration of the claimed esculoside is art-recognized result effective variables because it has slimming effect, which would have been routinely determined and optimized in the pharmaceutical art.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

Regarding Di Pierro reference, Applicant argues that "DI PIERRO requires at least a combination 4 vasoactive ingredients (plus one optional):

a) complex of escin/beta-sitosterol with phospholipids.

b) complex of *Gingko biloba* dimeric flavonoids with phospholipids,

c) complex of Centella asiatica triterpenes with phospholipids,

and optionally one or both of:

d) ethylximeninate, and

e) standardized *Coleus forskolli* extract.

DI PIERRO fails to disclose or suggest that any one component or combination of less than four is capable of producing the same effect" (page 9, last paragraph bridging page 9).

This is not found persuasive. DI PIERRO only contains 3 vasoactive ingredients not including the optional ingredients. Since claim 1 recites "the third vasoactive agent is at least one compound selected from the group consisting of …escin beta-sitosterol complexed with phosphollipid, …the Centella asiatica extract", thus the third vasoactive ingredient is allowed to have more than two compounds. Therefore, DI PIERRO only teaches the second vasoactive agent and the third vasoactive agent. In addition, optional compound should not be considered since it is optional the composition only contains the basic components.

The Declaration under 37 CFR 1.132 filed on 9/15/2008 is insufficient to overcome the current rejection because esculoside instead of visnadin is used in the current composition. This is not found persuasive. According to MPEP 716.02 (a), a greater than additive effect is not necessarily sufficient to overcome a prima facie case of obviousness because such an effect can

either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte* The NutraSweet Co., 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991). In the instant case, Applicant needs to present a side by side comparison between the claimed invention and the closest art to show the allegedly surprising results.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

QM

/Christopher R. Tate/
Primary Examiner, Art Unit 1655